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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,838	11/29/2004	Shmuel A. Ben-Sasson	24348-501 NATL	6386

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EXAMINER	
GUDIBANDE, SATYANARAYAN R	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/501,838	BEN-SASSON ET AL.	
	Examiner	Art Unit	
	Satyanarayana R. Gudibande	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15-20,26,27,31-50,53-56,63 and 68-83* is/are pending in the application.

4a) Of the above claim(s) *19,20,39-50,54-56,63,76,79, 80, 82 and 83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,15-18,26,27,31-38,53,68-75,77,78 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner inadvertently omitted claim 63 from being withdrawn from further consideration as being drawn to non-elected invention in the previous office action dated 2/7/06. Therefore, claim 63 has been hereby withdrawn from further consideration as being drawn to non-elected invention.

Response to Arguments/Remarks

Applicant's amendments to the claims 1, 34 and 53 and addition of claims 81-83 filed on 4/24/06 is acknowledged.

Claim Rejections - 35 USC § 103

Applicant's arguments filed 4/24/06 have been fully considered but they are not persuasive. The earlier obviousness rejection was made on the claims that were drawn to a penetrating peptide module comprising a penetrating peptide and an effector that is coupled or fused to said penetrating peptide, said penetrating peptide **comprising** (and not **consisting** as in presently amended claims), at least one amino acid sequence selected from the group consisting of SEQ ID Nos. 1-15, 24-29 and at least 12 contiguous amino acids of any of peptides in SEQ ID Nos. 1-15 and 24-29.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claim Rejections - 35 USC § 112

Applicant's arguments, see page 9, filed 4/24/06, with respect to indefiniteness have been fully considered and are persuasive. The rejection of 34 has been withdrawn.

Applicant's arguments with respect to claims 1, 10-13, 15-18, 26, 27, 3138, 53, 68-75, 77 and 78 have been considered but are moot in view of the new ground(s) of rejection.

Claims 82 and 83 are withdrawn from further consideration as being drawn to non-elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 15-18, 26, 31, 32, 53 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1 136 557 A1 of Schilfgaarde, et al.

In the instant application, applicants claim a penetrating module comprising a penetrating peptide and an effector that is coupled or fused to said penetrating peptide, said penetrating

peptide consisting of at least one amino acid sequence selected from the group consisting of SEQ ID Nos. 1-15, 24-29 and at least 12 contiguous amino acids of any of peptides in SEQ ID Nos. 1-15 and 24-29, wherein the penetrating peptide is capable of translocation across a biological barrier. The applicants further claim a pharmaceutical composition comprising the penetrating module and a pharmaceutically acceptable carrier. A kit for treating a disease comprising, therapeutically effective amount of the pharmaceutical composition.

The amino acid sequence of penetrating peptide SEQ ID No. 1, is known in the art (EP 1 136 557 A1 of Schilfgaarde, et al.). The reference discloses a penetrating peptide sequence (SEQ ID No. 4, page 19) that comprises the SEQ ID No. 1 of the instant application that crosses epithelial cell membranes. The two N-terminal amino acids and the amino acid residues 26-205 of the disclosed sequence could be an effector molecule because the effector molecule can be any bioactive molecule, and in this case it could be an antigen according to claim 18. Therefore, the disclosed sequence, SEQ ID No. 4 of Schilfgaarde, et al., consisting of penetrating peptide of SEQ ID No. 1 of the instant application wherein the effector molecule is fused into meets the limitation of the recited claims. The reference teaches that using recombinant techniques, paracytin peptides could be fused to other amino acid sequences such as therapeutically active peptides or proteins (page 9, lies 13-17). Schilfgaarde, et al., teaches the preparation of pharmaceutical compositions using paracytins with pharmaceutically acceptable carriers (page 8, [0079]-[0085]). Further the reference teaches that the pharmaceutical composition could be provided as a kit with the pharmaceutical composition containing the active substances to be administered (overlapping paragraph [0086] on pages 8 and 9]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 15-18, 26, 27, 31-38, 53, 68-75 77, 78 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 136 557 A1 of Schilfgaarde, et al., in view of Juliano, et al., Current Opinion in Molecular Therapeutics, 2000, 2, 297-303, in view of Lindgren, et al., TiPS, 2000, 21, 99-103, further in view of US 5,286,637 issues to Veronese as stated in our previous office action dated 2/7/06.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 31, 33, 34 and 53 provisionally rejected on the ground of nonstatutory double patenting over claims 1, 2, 90, 97, 101 and 102 of copending Application No. 10665184. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims are drawn to penetrating peptides and pharmaceutical compositions comprising the penetrating peptide and effector molecules.

Claims 1, 32, 35, 77 and 78 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 44, 64-68, 72 and 73 of copending Application No. 10942300. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims are drawn to penetrating peptides and pharmaceutical compositions comprising the penetrating peptide and effector molecules.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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